DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Food and Drug Administration
Washington, DC

Mr. Andrés Fletcher
General Manager
Marine Harvest
Ave. Diego Portales 1450
Puerto Montt, Chile

AUG 14 2003

Warning Letter

Dear Mr. Fletcher:

On November 20-21, 2002, we inspected your seafood processing facility, located in Ave. El Teniente 80, Puerto Montt, Chile. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Accordingly your aquaculture fresh & frozen salmon is adulterated, in that the product has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

In response to the observations listed in the form FDA-483, Mr. José Miguel Burgos, Head of Fisheries Health Department, SERNAPESCA, provided us with a copy of your document entitled [redacted] Upon review of the documentation provided to our investigator during the inspection and the documentation provided by Mr. Burgos, we find the following deviation concerning the aquaculture fresh & frozen salmon HACCP plan:

- You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as "the maximum or minimum value to which a physical biological, or chemical parameter must be controlled at a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's revised HACCP plan for fresh and frozen salmon (various market forms) lists a critical limit, "Raw material is accepted when a declaration of guarantee is presented indicating that the pharmaceutical residue levels are not higher that the destination markets permit[redacted]" at the Receiving of raw material critical control point that is inadequate to control the use of FDA unapproved aquaculture drugs. This is evidenced by the use of [redacted] on the salmon you process. Although you provided test results showing that the residuals from some of

these drugs are not detectable, FDA does not allow their use on seafood products destined for export to the United States. An appropriate critical limit should indicate that fish destined for export to the United States is not exposed to unapproved aquaculture drugs.

For additional information regarding control strategies associated with aquaculture drug use, please refer to the Fish and Fishery Products Hazards and Controls Guidance: *Third Edition*, Chapter 11 (Aquaculture Drugs), found at www.cfsan.fda.gov/~comm/haccp4.html.

- You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a HACCP plan that, at a minimum, lists the food safety hazards that are likely to occur, to comply with 21 CFR 123.6(a) and (c)(1). A food safety hazard is defined in 21 CFR 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm's HACCP plan for frozen, vacuum-packed, brine injected salmon portions does not list the food safety hazard of *Clostridium botulinum*. Although you are brining and freezing the vacuum packed fish that you process, your labels do not provide sufficient handling instructions. In addition to thawing under refrigeration, you should inform the consumer that it is important to open the individual vacuum packs immediately upon thawing. If you correctly label your retail packages, the hazard of *Clostridium botulinum* will not be considered reasonably likely to occur and would not need to be addressed in your HACCP plan. If the labeling for your packages is not corrected, you must control the hazard of *Clostridium botulinum*.

  For additional information regarding control strategies for *Clostridium botulinum* growth and toxin formation, please refer to the Fish and Fishery Products Hazards and Controls Guidance: *Third Edition*, Chapter 13 (*Clostridium botulinum* Toxin Formation), found at www.cfsan.fda.gov/~comm/haccp4.html.

Please respond in writing within six (6) weeks from receipt of this letter. Your response should outline the specific steps you are taking to correct these deviations. You should include in your response documentation such as a copy of your revised HACCP plan reflecting the changes you made and other useful information that will assist us in evaluating your corrections. If you cannot complete the correction before you respond, we expect that you will explain the reason for your delay and state when you will correct these deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulation and the Good Manufacturing Practice regulation (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Failure to respond adequately will result in your firm being placed on Detention Without Physical Examination.

Please send your reply to Food and Drug Administration, Attention: Giselle Jordan, Consumer Safety Officer, Office of Compliance, Division of Enforcement, Import Branch HFS-606, 5100 Paint Branch Parkway, College Park, MD 20740 U.S.A. If you have any questions regarding this letter, you may contact Ms. Jordan at (301) 436-1576 or via e-mail at gjordan@cfsan.fda.gov.

Sincerely,

Sonia A. Delgado for

Judith A. Gushee
Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition